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Medtronic Attn: Noreen C. Johnson, IP Legal Department 2600 Sofamor Danck Drive Memphis, TN 38132			EXAMINER NGUYEN, CAMTU TRAN	
			ART UNIT	PAPER NUMBER
			3772	
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			07/20/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/828,470

Applicant(s)

LAYNE ET AL.

Examiner

Camtu T. Nguyen

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 April 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4, 12, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4, 12, 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 July 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/C)
- Paper No(s)/Mail Date 4-16-09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is responding to applicant's amendment filed on 4/16/2009. Claims 1 & 24 have been amended.

Applicant amended claim 1 and remarked that the Reiley et al's platform does not open in a radial teach a side surface facing in the radial direction. In response, Figure 5K(1) illustrates the platform is open in a radial direction and that it has a side surface facing in the radial direction. Since claim 1 does not recite the dimension of the side surface nor define what constitute the side surface, the Reiley et al's interpretation of the platform meets applicant's claimed limitation, in particular, the platform/extension protrudes from circumferential wall and extends beyond distal end and is opened in a radial direction via holes (88).

The claims, as amended, have been carefully considered but deemed not allowable based on the following rejection(s) in view of an updated search.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the side surface of the platform recited in claim 1 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing

sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding claim 1, there is no disclosure support for claimed a platform **that is open in a radial direction and has a side surface in the radial direction.**

Regarding claim 24, there is no disclosure support for claimed **the extension protrudes from the distal end of the hollow body from only a relatively small circumferential portion of the circumferential wall of the hollow body.**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The term "relatively small" in claim 24 is a relative term which renders the claim indefinite. The term "relatively small" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Namely, it is unclear how the extension protrudes from the circumferential wall.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 12, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuslich et al (Publication No. US 2002/0010472 A1).

Kuslich et al discloses in Figures 1-10 a tool to direct bone replacement material, comprising a hollow tube (40) having an extension that protrudes from the circumferential wall beyond the tube's (20) distal end and forms a platform. The embodiment of Figures 9-11 illustrates the platform opens in a radial direction and has a side surface facing in the radial direction. Figure 4 illustrates the expandable structure (10) for forming a cavity. Figure 8 illustrates the hollow tube (20, 40) filled with bone replacement material (26). Paragraph 28 teaches the bone replacement material (26) is of bone cement. The Kuslick et al device would perform steps recited in method claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4, 12, 23, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al (U.S. Patent No. 6,248,110).

Reiley et al discloses in Figures 1 and 2 a vertebral body (26) includes an exterior forms from compacted cortical bone (28) which encloses an interior volume (30) of cancellous bone (32).

With regards the extension protruding from the circumferential wall and beyond the distal end, according to applicant's the specification on page 15 lines 6-7, the extension is the platform, structurally. In addition, the specification on page 15 lines 16-17 discloses the platform (220)

could be formed integrally with the hollow member (210), thus, for purposes of broad interpretation of the latter disclosure, it is reasonable for one skilled in the art to interpret the Reiley's Figure 5k(1) is consistent with applicant's specification. Furthermore, applicant's Figure 2, tool (200) comprising a distal end (250), an extension/platform (220) protrudes from tool's (200) wall and beyond the distal end (250). Applicant's Figure 2 illustrates the distal end (250) is closer to the tool's (200) proximal end than the extension/platform (220). See illustration below.

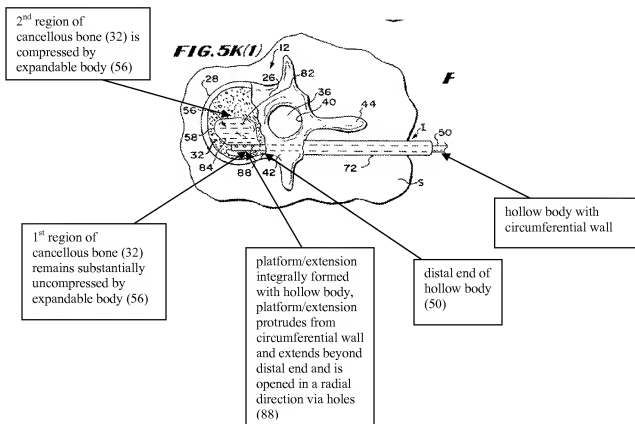


Figure 5K(1) illustrates the catheter (50) introduced into the interior volume (30) occupied in the cancellous bone (32) and the expandable body (56) expanding on one side of the distal end of the catheter (50).

Figure 5K(1) illustrates the platform/extension induce the expandable body (56) from expanding in more than one direction and expanding from the distal end towards the platform/extension. Figure 7 illustrates the injector tip (90) occupying in cavity (84) while the expandable body (56) collapses and the injector tip (90) injects filler material into the cavity (84).

With regards to the 1st step in claim 1 reciting the **platform that is open in a radial direction and has a side surface facing in the radial direction**, Figure 5K(1) illustrates the platform is open in a radial direction and that it has a side surface facing in the radial direction via holes (88).

With regards to the 5th step in claim 1 reciting the platform "serving as a barrier to induce the expandable structure to expand away from the platform in the at least one radial direction to compress the second region of the cancellous bone, while the first region of the cancellous bone remains substantially not compressed", the Reiley et al's extension/platform (see illustration above) would serve as a barrier for purposes of inducing the expandable body (56) to expand away from the extension/platform in one radial direction to compress the 2nd region of cancellous bone (32) while the 1st region remains substantially not compressed.

With regards to claim 12, bone filling material, such as artificial bone substitute or flowable synthetic bone material or methyl methacrylate bone cement is known in the art of bone filling.

With regards to claim 24, Figure 5K(l) of the Reiley et al illustrates the extension/platform (see illustration above) extends beyond the catheter tube (50) from only a circumferential portion of the catheter tube's (50) circumferential wall, particularly when the extension/platform extends at central point of hole (88), thereby, rendering the extension/platform extending from only a circumferential portion of the catheter tube's (50) circumferential wall and not the entire circumferential wall.

The recitation "a method" has not been given patentable weight because it has been held that a preamble is denied the effect of a limitation where the claim is drawn to a structure and the portion of the claim following the preamble is a self-contained description of the structure not depending for completeness upon the introductory clause. *Kropa v. Robie*, 88 USPQ 478 (CCPA 1951).

Clearly, the illustration of Reiley et al's Figure 5K(l) interpreted above discloses applicant's invention.

The Reiley et al device would perform steps recited in method claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Camtu T. Nguyen whose telephone number is 571-272-4799. The examiner can normally be reached on (M-F) 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Camtu T. Nguyen/
Examiner, Art Unit 3772

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772